

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Sterile Isotonic Solution of Sodium Chloride for Parenteral Use," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: July 30, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1974. Adulteration of redistilled water. U. S. v. 10,000 Ampuls of Redistilled Water. Consent decree of condemnation and destruction. Product ordered released under bond for salvage of the containers. (F. D. C. No. 19259. Sample No. 3268-H.)

LIBEL FILED: March 1, 1946, District of Maryland.

ALLEGED SHIPMENT: On or about December 29, 1945, by Torigian Laboratories, Inc., from New York, N. Y.

PRODUCT: 10,000 ampuls of *redistilled water* at Perry Point, Md.

LABEL, IN PART: "Water Redistilled N. F. Sterile."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ampuls of Redistilled Water," a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the standard set forth therein since it was contaminated with undissolved material.

DISPOSITION: September 13, 1946. Torigian Laboratories, Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for the salvage of the containers, after the destruction of the contents under the supervision of the Food and Drug Administration.

1975. Adulteration of B-Parplex. U. S. v. 57 Vials, 9 Vials, and 8 Vials of B-Parplex. Default decree of condemnation and destruction. (F. D. C. No. 20060. Sample Nos. 45742-H, 45780-H, 45781-H.)

LIBEL FILED: June 7, 1946, Northern District of California.

ALLEGED SHIPMENT: On or about January 18 and April 12 and 16, 1946, by the Intra Products Co., from Denver, Colo.

PRODUCT: 66 30-cc. vials and 8 15-cc. vials of *B-Parplex* at San Francisco, Calif.

LABEL, IN PART: "Sterile Solution B-Parplex No. 5 [or "No. 7"]."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported to possess since it purported to be for intravenous use and contained undissolved material. Substances purporting to be appropriate for intravenous use should be free from undissolved material.

DISPOSITION: July 25, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1976. Adulteration of Theobromine—Ioform with Phenobarbital. U. S. v. 45,000 Tablets of Theobromine—Ioform with Phenobarbital. Default decree of forfeiture and destruction. (F. D. C. No. 18272. Sample No. 23782-H.)

LIBEL FILED: November 1, 1945, Western District of Texas.

ALLEGED SHIPMENT: On or about June 27, 1945, by the Drug Products Co., from Long Island City, N. Y.

PRODUCT: 45,000 tablets of *Theobromine—Ioform with Phenobarbital* at San Antonio, Texas. Samples of this product were found to contain not more than 0.35 grain of phenobarbital per tablet.

LABEL, IN PART: "Theobromine—Ioform with Phenobarbital ½ Grain."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess.

DISPOSITION: January 25, 1946. No claimant having appeared, judgment of forfeiture was entered and the product was ordered destroyed.

1977. Adulteration and misbranding of Pyo-Gon Iodophenols. U. S. v. 57 Bottles of Pyo-Gon Iodophenols. Default decree of destruction. (F. D. C. No. 20396. Sample No. 47453-H.)

LIBEL FILED: July 15, 1946, District of Utah.

ALLEGED SHIPMENT: On or about April 28 and May 3 and 8, 1946, by Fred M. Potts and Co., from Los Angeles, Calif. A booklet entitled "Pyo-Gon" was received from the shipper during February 1946.

PRODUCT: 57 pint bottles of *Pyo-Gon Iodophenols* at Salt Lake City, Utah.

LABEL, IN PART: (Bottle) "Pyo-Gon Iodophenols No Free Phenol or Iodine, Analgesic Antiseptic Non-Irritating, Non-Toxic"; (Booklet) "Germicide, Antiseptic Phenol Coefficient—110."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, since it was not an antiseptic or a germicide and did not possess a phenol coefficient of 110.

Misbranding, Section 502 (a), the designation "Pyo-Gon" was false and misleading since it represented and suggested and created in the mind of the reader the impression that the article would be effective for the treatment of pus conditions, whereas it would not be effective for such purposes; and the label statement "Iodophenols No Free Phenol" was false and misleading since the article contained no iodophenol, but did contain free phenol.

DISPOSITION: August 30, 1946. No claimant having appeared, judgment was entered and the product was ordered destroyed.

1978. Adulteration and misbranding of tooth powder. U. S. v. 34 Cans of Tooth Powder. Default decree of condemnation and destruction. (F. D. C. No. 20290. Sample No. 38660-H.)

LIBEL FILED: June 21, 1946, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about June 11, 1945, by the International Pyorrhea Corporation of Illinois, from Chicago, Ill.

PRODUCT: 34 cans of *tooth powder* at Milwaukee, Wis. Examination showed that the product consisted essentially of salt, sodium bicarbonate, borax, bismuth trioxide, starch, methyl salicylate, and oil of cloves. Examination showed also that the article was not germicidal and antiseptic.

LABEL, IN PART: "Zipco, Prevents Pyorrhea * * * Germicidal and Antiseptic."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess.

Misbranding, Section 502 (a), the label statements, "Prevent Pyorrhea * * * Heals Abrasions of the Gums * * * Hardens Soft Gums and Stops Bleeding * * * Germicidal and Antiseptic * * * If the powder causes pain or discomfort, it proves that infection is present," were false and misleading. The product would not be effective to accomplish the results stated and implied. Further misbranding, Section 502 (b) (2), the product failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (e) (2), it was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

DISPOSITION: August 7, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1979. Adulteration and misbranding of prophylactics. U. S. v. 151 Gross of Rubber Prophylactics. Default decree of condemnation and destruction. (F. D. C. No. 17889. Sample No. 23294-H.)

LIBEL FILED: October 12, 1945, Eastern District of Arkansas.

ALLEGED SHIPMENT: On or about June 6, 1945, by the William Nesbit Co., from Pittsburgh, Pa.

PRODUCT: 151 gross of rubber *prophylactics* at Little Rock, Ark. Examination of 108 samples showed that 5.6 percent were defective in that they contained holes.

LABEL, IN PART: "Silverlatex Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: November 19, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.